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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,425	07/03/2001	Roberto Valducci	242/9-1568	1890

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William J. Sapone, Esq.
Coleman Sudol Sapone P.C.
714 COLORADO AVENUE
BRIDGEPORT, NY 06605-1601

EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/898,425		ROBERTO VALDUCCI	
	Examiner		Art Unit	
	Blessing M. Fubara		1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-20 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges receipt of preliminary amendment A filed 07/03/01.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 15, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 18 and 19 contain the trademark/trade name EUDRAGIT. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe hydroxypropylmethyl cellulose phthalate, or hydroxypropylmethylcellulose acetate succinate and, accordingly, the identification/description is indefinite.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10

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USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad limitation 10-60%, and the claim also recites 30-35 which is the narrower statement of the range/limitation.

"Preferably" in claim 3 is indefinite and confers to the claim range within a range.

The term "characterized by" in line 2 of claim 1 is indefinite and makes the claim unclear. However, the claim is examined as a formulation comprising an active ingredient and polymers or mixtures of polymers where each polymer is soluble at from pH 6 to 7,

It is unclear what applicant wants to convey by underlining "characterized by" in line 2 of claim 1.

4. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in

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section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 1-6, 8, 15, 18 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Watts (US 6,228,396).

Watts discloses a colonic drug delivery composition (abstract). The composition comprises active agents such as hydrocortisone, budenonide, cisapride, anticholinergics, opioids and calcium channel blockers and the composition can also be used to deliver antiviral agents for HIV (column 4, lines 32-61). The formulation delivered either as tablets or starch capsules are coated and the coating composition is enteric (pH sensitive) where the coating composition is selected from cellulose acetate trimellitate, hydroxypropylmethyl cellulose phthalate, polyvinyl acetate phthalate and shellac (column 1, lines 48-67, column 2, lines 4-8, lines 32-64 and column 3, lines 12-20). Watts suggests optimizing the coating composition to maximize disintegration (column 2, lines 61-64). Mesalazine tablets coated with EUDRAGIT are known and dissolve above pH 6:00. Claims are broadly directed to active agents and polymer and a composition meeting the limitations of claim 1 would have the release profile recited in claim 3. Therefore, Watts anticipates the claims.

7. Claims 1-3, 5, 6, 8, 15, 16, 18 and 19 rejected under 35 U.S.C. 102(e) as being anticipated by Yajima et al. (US 5,972,373).

Yajima teaches a composition comprising macrolide antibiotics (column 2, lines 38-48) and polymers (column 2, lines 55-57). The composition is formulated into granules, powders, capsules, tablets and dry syrups (column 3, lines 15-18) and these formulations are enteric coated (column 3, line 48). The composition further comprises excipients (mannitol,

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carboxymethylcellulose), disintegrants (starch and crystalline cellulose), binders (hydroxypropylmethyl cellulose and propyleneglycol alginate), lubricants (stearic acid) and antioxidant (BHT, BHA and alpha-tocopherol and citric acid). See column 3, lines 1-48). The coating agent includes hydroxypropylmethyl cellulose phthalate, hydroxypropylmethyl cellulose acetate succinate and the composition further comprises dyestuff and titanium oxide (column 3, lines 58 and 59). Claims are broadly directed to active agents and polymer and a composition meeting the limitations of claim 1 would have the release profile recited in claim 3. Thus, Yajima anticipates the claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watts (US 6,228,396) in view of Ishizuka et al. (US 6,160,017) or Ishizuka et al. (US 6,160,017) in view of Watts (US 6,228,396).

Watts is discussed above. Watts does not teach a multilayer-tablet formulation but discloses that the formulation can be used for treating ulcerous colitis and/or Crohn's disease.

However, Ishizuka discloses a composition comprising conagenin or a pharmaceutically acceptable salt thereof (abstract). The composition further comprises carriers and some of the excipients listed are lactose, starch, crystalline cellulose, silicic acid, shellac, methylcellulose,

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polyvinylpyrrolidone, stearic acid, and polyethylene glycol (column 3, lines 45-62). The composition is formulated into multiplayer-coated tablets and the tablets are enteric coated, sugar coated or gelatin coated (column 3, lines 63-67). This composition is used for treating ulcerous colitis and/or Crohn's disease.

Watts and Ishizuka separately teach separate compositions for treating ulcerous colitis and/or Crohn's disease. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it is prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Watts in the manner disclosed by Ishizuka or Ishizuka in the manner taught by Watts. Since both prior art references teach formulations for treating ulcerative colitis and/or Crohn's disease, one having ordinary skill in the art would have been motivated to prepare a multi layered tablet formulation comprising, active agents such as hydrocortisone, mesalazine, budenonide, cisapride, anticholinergics, opioids, conagenin and calcium channel blockers, coating composition selected from cellulose acetate trimellitate, hydroxypropylmethyl cellulose phthalate, polyvinyl acetate phthalate and shellac and stearic acid to provide a third composition from the combined teachings of Watts and Ishizuka to treat ulcerous colitis and/or Crohn's disease. The expected result is a multi layered tablet formulation comprising active agents, polymers or mixtures of polymer and carrier.

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10. Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374.

The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
February 25, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600